REMARKS

Regarding the Status of the Claims:

Claims 10 – 12, 14 – 18, and 20 – 24 are pending.

Claims 1 – 9, 13, 19, and 25 – 28 are canceled.

No claims have been withdrawn from consideration.

Regarding the Claim Rejections:

The Office action rejects:

I. claims 10 – 12, 14 – 18, 20 and 22 – 24 under 35 U.S.C §103(a) over US 4,127,422 to Guzi Jr. et al. (hereinafter, "Guzi"), US 5,858,412 to Staniforth et al. (hereinafter, "Staniforth"), and US 6,086,915 to Zeligs et al. (hereinafter, "Zeligs"); and

II. claims 10, 15, 16, 18, 20 and 21 under 35 U.S.C §103(a) over US 6,066,334 to Kolter et al. (hereinafter, "Kolter"), Staniforth, and Zeligs.

Regarding Rejection I:

Applicants respectfully submit that the rejection of claims 10 – 12, 14 – 18, 20 and 22 – 24 under 35 U.S.C §103(a) over Guzi, Staniforth, and Zeligs should be withdrawn.

The rejection seems to be based on a simple misreading of the claims. Independent claim 10 relates to a process for producing an excipient adapted for use in a solid pharmaceutical dosage form.[1] The excipient produced by the process must be in the form of a free-flowing powder.[2] The excipient must consist essentially of a pharmaceutically acceptable polymer, and from 10 to 50% by weight, based on the total

[1] Specification, page 1, lines 1 – 2.
[2] Specification, page 4, lines 20 – 21.

weight of said excipient, of a liquid or semisolid solubilizing surface-active substance.[3] Similarly, independent claim 22 relates to a process for producing a free-flowing powder excipient for use in a solid pharmaceutical dosage form.[4] The free-flowing powder excipient produced according to the process must consist essentially of a pharmaceutically acceptable polymer, and from 10 to 50% by weight, based on the total weight of the excipient, of a liquid or semisolid solubilizing surface-active substance.[5] However, the Office action inadvertently misreads the claims as reciting "a process for making an excipient comprising spray drying a composition comprising 10 – 50% of a surfactant and a vinylpyrrolidone polymer."

Applicants respectfully submit that this misreading is significant. "The transitional term 'comprising,' which is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps."[6] On the other hand, "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention."[7] Applicants respectfully submit that the transitional phrase "consisting essentially of" excludes certain materials which would necessarily be present in any excipient produced according to the proposed combination of references. More specifically, applicants respectfully submit that the high amounts of solid pigment particles required by Guzi are excluded by the transitional phrase "consisting essentially of." High amounts of solid pigment particles, as required by Guzi, are excluded, because, as discussed in more detail below, high amounts of solid pigment particles would materially affect the basic and novel characteristics of the claimed invention.

The claimed invention achieves results that a person of ordinary skill in the art would not have expected at the time the present invention was made. As expressed on pages 1 and 2 of the specification, adding more than 10% by weight of a liquid or semisolid solubilizing surface-active substance to a polymeric carrier was expected to cause processability problems, because of the waxy consistency of the resultant

[3] Specification, page 2, lines 9 – 14.
[4] Specification, page 1, lines 1 – 2.
[5] Specification, page 2, lines 9 – 14.
[6] MPEP §2111.03.
[7] MPEP §2111.03, citing *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

formulation. This expectation is also expressed on page 2 of the enclosed Declaration under 37 C.F.R. §1.132 by Dr. Karl Kolter. While acknowledging that willful false statements are punishable by fine and/or imprisonment, and that willful false statements may jeopardize the validity of any patent issuing from the present application, Dr. Kolter has declared,

> [l]iquid and semi-solid surface-active substances and pharmaceutical formulations comprising such substances are often difficult to handle because of the wax-like and sticky consistency of the masses. These surface-active substances also have a plastifying effect. Especially in case of formulation mixtures for direct compression to tablets such surface-active substances have hitherto caused problems.

Appellants respectfully submit, "[a] greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue."[8] Similarly, "[a]bsence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness."[9] Such is the case with the present invention. As further declared by Dr. Kolter,

> [i]t was unexpected that the excipients obtained either by spray-drying or by melt extrusion turned out to be free-flowing powders that can easily be processed without restriction to give solid dosage forms. Furthermore it was unexpected that the excipients could be processed by spray drying. An ordinarily skilled expert would certainly have expected that especially spray-drying of a solution of the two specific components in the claimed amounts would not work at all because of the plastifying properties of the surface-active substances.

First, in light of what a person of ordinary skill in the art would have expected, Examples 1 – 3 provide evidence of unexpected results that are commensurate in scope with the claimed invention, and establish the non-obviousness thereof. It is also noted that "[e]vidence of unexpected results must be weighed against evidence supporting

[8] MPEP §716.02(a), citing *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985).
[9] MPEP §716.02(a), citing *Ex parte Mead Johnson & Co.* 227 USPQ 78 (Bd. Pat. App. & Inter. 1985).

prima facie obviousness in making a final determination of the obviousness of the claimed invention."[10]

Second, applicants respectfully submit that the unexpected results discussed above clarify the importance of the transitional phrase, "consisting essentially of." Again, "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention."[11] Applicants respectfully submit that the pigment required by Guzi is excluded by the transitional phrase "consisting essentially of." Guzi requires 55 – 80 % by weight of a pigment. The water-insoluble pigment is dispersed in an aqueous medium together with a surface-active substance and a polymer. The dispersion is dried by a spray-drying process. As expressed in the Kolter declaration, "[s]ince the spray-dispersion contains such a high amount of solid pigment particles spray-drying is not considered as a problem by a skilled expert." In other words, the presence of high amounts of solid pigment particles materially affect the basic and novel characteristics of the claimed invention. As such, the presence of high amounts of solid pigment particles is excluded by the claim language, which employs the transitional phrase, "consisting essentially of."

Any excipient produced according to the proposed combination of Guzi, Staniforth, and Zeligs would necessarily comprise high amounts of solid pigment particles. The claim language excludes high amounts of solid pigment particles. Thus, the proposed combination does not obviate the claimed invention.

Applicants also respectfully submit that the proposed combination would also fail to meet at least one other claim requirement. The proposed combination involves spray-drying a dispersion with a high content of solids. On the other hand, independent claim 10 relates to a process for producing an excipient adapted for use in a solid pharmaceutical dosage form.[12] The process comprises either spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer,[13] or processing the polymer and the surface-active substance in an extruder to obtain a

[10] MPEP §716.02(c), citing *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978).
[11] MPEP §2111.03, citing *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).
[12] Specification, page 1, lines 1 – 2.
[13] Specification, page 3, lines 31 – 37.

homogeneous melt[14] and subsequently converting the melt into the free-flowing powder.[15] Similarly, independent claim 22 relates to a process for producing a free-flowing powder excipient for use in a solid pharmaceutical dosage form.[16] The process comprises producing the free-flowing powder excipient by one of: spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer,[17] or extruding the polymer and the surface-active substance to obtain a homogeneous melt[18] and subsequently converting the melt into the free-flowing powder.[19]

Finally, the Kolter declaration explains that a skilled artisan had no apparent reason to make the proposed combination at all. It seems straightforward, that the references are in a different field than the present invention. Thus, the question is whether the references would have logically commended themselves to the attention of a person of ordinary skill in the art, when trying to solve the problem addressed by the present invention. As expressed in the declaration, a skilled artisan would not have looked to these references for guidance.

For at least these reasons, applicants respectfully submit that the claimed invention is nonobvious over the proposed combination.

Regarding Rejection II:

Applicants respectfully submit that the rejection of claims 10, 15, 16, 18, 20 and 21 under 35 U.S.C §103(a) over Kolter, Staniforth, and Zeligs. should be withdrawn. Applicants respectfully submit that this rejection seems to be predicated on the same misreading of the claims, as discussed above with regard to Rejection I, whereby the transitional phrase "comprising" was inadvertently substituted for the transition phrase "consisting essentially of." With this important distinction in mind, applicants respectfully submit that the proposed combination would require from 10 – 95% by

[14] Specification, page 3, line 44 – page 4, line 2, and Example 2.
[15] Specification, page 4, lines 4 – 11, lines 20 – 21, and Example 2.
[16] Specification, page 1, lines 1 – 2.
[17] Specification, page 3, lines 31 – 37.
[18] Specification, page 3, line 44 – page 4, line 2, and Example 2.
[19] Specification, page 4, lines 4 – 11, lines 20 – 21, and Example 2.

weight of polyvinylacetate, as described by Kolter. At column 2, lines 57 – 60, Kolter explains that the polyvinyl acetate is not miscible with the N-vinylpyrrolidone-containing polymer. At column 2, lines 56 – 57, Kolter explains that polyvinyl acetate markedly increases the plasticity in the final product. Thus, applicants respectfully submit that the 10 – 95 % by weight of polyvinyl acetate is excluded by independent claim 10, which relates to a process for producing an excipient that must consist essentially of a pharmaceutically acceptable polymer, and from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance.[20] The other rejected claims depend from claim 10 and are also nonobvious.

In Conclusion:

The present application is in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

NOVAK DRUCE + QUIGG, LLP
1300 Eye St. N.W.
Suite 1000 West
Washington, D.C. 20005

Phone: (202) 659-0100
Fax: (202) 659-0105

Respectfully submitted,
NOVAK DRUCE + QUIGG, LLP

Michael P. Byrne
Registration No. 54,015

ENCLOSURE (1): Declaration under 37 C.F.R. §1.132 by Dr. Karl Kolter.

[20] Specification, page 2, lines 9 – 14.